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INTEGRATIVE THERAPEUTICS INC."

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9755 SW Commerce Circle, Suite B2
Wilsonville, OR 97070
P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY* & PHYTOPHARMICA*

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

MAY 1 2 2004

April 25, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards	Body Rewards Healthy Skin contains all-	Omega-6 (Linoeleic Acid) (LA), Omega-3
Healthy Skin™*	natural oils rich in Omega-9, Omega-6 and	(Alpha-Linolenic Acid) (ALA),
	Omega-3 fatty acids, nutrients known to	Eicosapentaenoic Acid (EPA), Omega-9
	support the lipid (fat) composition and	(Oleic), Gamma-Linolenic Acid (GLA),
	physical properties of healthy skin.*	Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Зу:	This was	
•	Robert Doster Senior Vice President of Scientific Affairs	
Date:	4/25/04	

Commence Continues (Section 1984)

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Sincerely,



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April 25, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards Healthy Skin™*	Supports the lipid composition and physical properties of healthy skin*	Omega-6 (Linoeleic Acid) (LA), Omega-3 (Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/25/04

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Sincerely,



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April 26, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE
Body Rewards Healthy Skin™*	While polyunsaturated fats from fish, flax and other oils support many body systems, intake of saturated fats from animal sources (beef or pork) does not have the same documented health supportive effects.*	Omega-6 (Linoeleic Acid) (LA), Omega-5 (Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation th the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/26/04

Sincerely,



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April 27, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards	Many followers of low-carbohydrate diets	Omega-6 (Linoeleic Acid) (LA), Omega-3
Healthy Skin™*	build their daily nutrition intake around consumption of fried, fatty animal protein foods (steak, hamburgers, bacon, etc). While this may indeed lead to a loss in body weight, it also causes a less than optimal intake of essential fatty acids, the "good" fats that support the heart, immune system, brain function, and also healthy skin and hair.*	(Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	Toke to the L		
-	Robert Doster		
Title:	Senior Vice President of Scientific Affairs		
Date:	4/27/04		
Date:	1/0/10/		

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April 27, 2004

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PRODUCTNAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards	There is an abundance of statistically	Omega-6 (Linoeleic Acid) (LA), Omega-3
Healthy Skin™*	significant evidence demonstrating health	(Alpha-Linolenic Acid) (ALA),
	supportive benefits from Omega-3, Omega-	Eicosapentaenoic Acid (EPA), Omega-9
	6 and Omega-9 essential fatty acids.*	(Oleic), Gamma-Linolenic Acid (GLA),
		Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	RUCUL
Title:	Robert Doster Senior Vice President of Scientific Affairs
Date:	4/21/04

Sincerely,



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April 28, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards Healthy Skin™*	Diets rich in Omega-9, Omega-6, and Omega-3 essential fatty acids provide significant health benefits for skin.* In laboratory research, these essential fatty acids rapidly incorporate into cell membranes and profoundly influence biological responses.*	Omega-6 (Linoeleic Acid) (LA), Omega-3 (Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are transful and notinisleading.

By:	•
-	Robert Doster
Title:	Senior Vice President of Scientific Affairs
_	4/28/04
Date:	7128109

Sincerely,



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ENZYMATIC THERAPY & PHYTOPHARMICA*

April 28, 2004

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards Healthy Skin™*	Several studies have shown that supplement fish oil helps retain skin appearance and elasticity after exposure to sunlight (UV radiation.)*	Omega-6 (Linoeleic Acid) (LA), Omega-3 (Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/28/04

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Sincerely, Michael P. Sweum



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PRODUCT NAME		INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards	A review of well-controlled clinical studies	Omega-6 (Linoeleic Acid) (LA), Omega-3
Healthy Skin™*	and other human research shows that	(Alpha-Linolenic Acid) (ALA),
,	Omega-9, Omega-6, and Omega-3	Eicosapentaenoic Acid (EPA), Omega-9
	consumption provides many additional	(Oleic), Gamma-Linolenic Acid (GLA),
	health supportive benefits, including support	Docosahexanoic Acid (DHA)
	of immune function, mental health, and the	· · ·
	retention of healthy cholesterol levels that	
	are already within normal limits.*	

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert Doster

กระที่ 20 ของเพราะสีเลิกที่โดยสี**ส**าก

Title: Senior Vice President of Scientific Affairs

Date: 4/29/04

Sincerely,



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PRODUCT NAME		INGREDIENT(S) TO WHICH THE CLAIM REFERS
Body Rewards Healthy Skin™*	A recent clinical study found that following a low-carbohydrate diet, plus consumption of fish and flax oil led to greater weight loss and better heart health than following a traditional low fat diet.*	Omega-6 (Linoeleic Acid) (LA), Omega-3 (Alpha-Linolenic Acid) (ALA), Eicosapentaenoic Acid (EPA), Omega-9 (Oleic), Gamma-Linolenic Acid (GLA), Docosahexanoic Acid (DHA)

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By:	fuld lister
-	Robert Doster Senior Vice President of Scientific Affairs
Date:	4/29/04

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